

## **I. Legal Authority**

These regulations are proposed under the authority of 25 U.S.C. 198, 231, and 1661; 42 U.S.C. 243, 248, 249, 264-272, and 2001.

## **II. Background and Purpose**

The primary authorities supporting this rulemaking are §§ 361-368 of the Public Health Service Act (42 U.S.C. 264-271). Section 361 authorizes the Secretary to make and enforce regulations as are necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States and from one State or possession into another.

Recent experiences with emerging infectious diseases such as West Nile Virus, SARS, and monkeypox have illustrated the rapidity with which disease may spread throughout the world and the impact communicable diseases, when left unchecked, may have on the global economy. As noted by the Institute of Medicine, National Academy of Sciences in a recent study, “Whether naturally occurring or intentionally inflicted, infections can cause illness, disability, and death in persons while disrupting whole populations, economies, and governments. And because national borders offer trivial impediment to such threats, especially in the highly interconnected and readily traversed “global village” of our time, one nation’s problem soon becomes every nation’s problem.” (Microbial Threats to Health: Emergence, Detection and Response”, Institute of Medicine, March, 2003). As diseases evolve naturally or as a result of human intervention, it is important to ensure that containment procedures reflect new threats and uniform ways to respond to them.

Stopping an outbreak—whether it is naturally occurring or intentionally caused—requires the use of the most rapid and effective public health tools available. These tools include basic public health practices such as disease reporting requirements and identification and notification of contacts who may have been exposed to a communicable disease so that they may receive preventive measures. Quarantine is defined as the restriction of the movement of persons exposed to infection to prevent them from infecting others, including family members, friends, and neighbors. Quarantine of exposed persons may be the best initial way to prevent the uncontrolled spread of highly dangerous biologic agents such as smallpox, plague, and Ebola fever—especially when combined with other health strategies such as vaccination, prophylactic drug treatment, patient isolation, and other appropriate infection control measures. Quarantine may be particularly important if a biologic agent has been rendered contagious, drug-resistant, or vaccine-resistant through bioengineering, making other disease control measures less effective.

The Secretary's authority to quarantine persons is limited to those communicable diseases published in an Executive Order of the President. This list currently includes cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, and viral hemorrhagic fevers, such as Marburg, Ebola and Congo-Crimean, Severe Acute Respiratory Syndrome, and influenza caused by novel or reemergent influenza viruses that are causing or have the potential to cause a pandemic (see Executive Order 13295, as amended by Executive Order 13375 on April 1, 2005).

Regulations that implement federal quarantine authority are currently promulgated in 42 CFR Parts 70 and 71. Part 71 deals with foreign arrivals and Part 70

deals with interstate matters. The Secretary has delegated to the Director of the Centers for Disease Control and Prevention the authority for implementing 42 CFR Part 71, which was last substantively updated in 1985. On August 16, 2000, the Secretary transferred the authority for interstate quarantine over persons from FDA to CDC, which became 42 CFR Part 70. FDA retained, pursuant to 21 CFR part 1240, regulatory authority over animals and other products that may transmit or spread communicable diseases. The Secretary took this action in order to consolidate regulations designed to control the spread of communicable diseases, thereby increasing the agencies' efficiency and effectiveness. This proposed rule is not intended to have any effect upon FDA's authority in 21 CFR part 1240. In 2003, in response to the emergence of Severe Acute Respiratory Syndrome (SARS), Health and Human Services (HHS) amended 42 CFR 70.6 and 71.3 to incorporate by reference the Executive Order listing the communicable diseases subject to quarantine, thereby eliminating the administrative delay involved in separately publishing the list of diseases through rulemaking. Also in 2003, CDC published an interim final rule that added §71.56 African rodents and other animals that may carry the monkeypox virus. Finally, on January 25, 2005, the Secretary added section 70.9 to establish vaccination clinics and a user fee in connection with administration of vaccine services and vaccine.

The intent of the proposed updates to 42 CFR Parts 70 and 71 is to clarify and strengthen existing procedures to enable CDC to respond more effectively to current and potential communicable disease threats.